

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (withdrawn): A method for joining and holding portions of a stomach to each other in the performance of a Nissen fundoplication procedure, the procedure requiring grasping the fundus of the stomach at a proximal location and pulling the fundus around the esophagus, wrapping the fundus around the esophagus one time and attaching the proximal stomach to an apposing portion of the stomach, the attachment made using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture into tissue of the proximal stomach;
- (b) pushing the first end of the suture through the stomach tissue until the first end of the suture extends out of the tissue at an exit point on the exterior of the stomach;
- (c) gripping and pulling the first end of the suture to draw the first portion of the suture through the tissue until the second axial location is proximate to the point of insertion of the first end of the suture and leaving a length of the first portion of the suture in the tissue between the point of insertion and exit point of the first end;
- (d) gripping the proximal stomach and wrapping the fundus around the esophagus until the proximal stomach contacts an apposing portion of stomach;
- (e) inserting the second pointed end of the suture into tissue of the apposing stomach;

- (f) pushing the second end of the suture through the stomach tissue until the second end of the suture extends out of the tissue at an exit point on the exterior of the stomach; and
- (g) gripping and pulling the second end of the suture to draw the second portion of the suture through the tissue until the second axial location is proximate to the point of insertion of the second end of the suture and leaving a length of the second portion of the suture in the tissue between the point of insertion and exit point of the second end.

Claim 2 (withdrawn): A method for joining and holding portions of a stomach to each other in the performance of a Nissen fundoplication procedure, the procedure requiring grasping the fundus of the stomach at a proximal location and pulling the fundus around the esophagus, wrapping the fundus around the esophagus one time and attaching the proximal stomach to an apposing portion of the stomach, the attachment made using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, and using an insertion device including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

- (a) gripping the proximal stomach and wrapping the fundus around the esophagus until the proximal stomach contacts an apposing portion of stomach and forms a junction of the proximal and the apposing stomach tissues;
- (b) inserting the first pointed end of the suture and leading end of the insertion device into stomach tissue at a point laterally spaced from the junction and on a first side of the junction;
- (c) pushing the first end of the suture and leading end of the insertion device through the first side of stomach tissue and penetrating the stomach tissue on a second side of the junction until the portion of the suture between the first and second axial locations is proximate to the junction; and
- (d) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place.

Claim 3 (withdrawn): A method for joining and holding portions of a stomach to each other in the performance of a Nissen fundoplication procedure, the procedure requiring grasping the fundus of the stomach at a proximal location and pulling the fundus around the esophagus, wrapping the fundus around the esophagus one time and attaching the proximal stomach to an apposing portion of the stomach, the attachment made using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) gripping the proximal stomach and wrapping the fundus around the esophagus until the proximal stomach contacts an apposing portion of stomach and forms a junction of the proximal and the apposing stomach tissues;
- (b) inserting the first pointed end of the suture into the tissue at a first side of the junction;
- (c) pushing the first end of the suture through the tissue until the first end of the suture extends out of the tissue at an exit point in the face of the junction below the surface of the tissue at the first side of the junction;
- (d) gripping the first end of the suture and pulling the first end out of the tissue for drawing the first portion of the suture through the tissue until the second axial location is at the point of insertion of the first end of the suture and leaving a length of the first portion of the suture in the tissue between the point of insertion in the first side of the junction and the exit point in the face of the junction at the first side of the junction;
- (e) inserting the first end of the suture into the face of the tissue below the surface of the tissue at a second side of the junction;

- (f) pushing the first end of the suture through the tissue until the first end of the suture extends out of the tissue at an exit point on the second side of the junction longitudinally spaced in a first direction from the insertion point in the first side of the junction;
- (g) gripping the first end of the suture and pulling the first end out of the tissue for drawing the first portion of the suture through the tissue while bringing the two sides of the junction together to a closed position along the first portion of the suture in the tissue and leaving a length of the first portion of the suture in the tissue between the point of insertion in the first side of the junction and the exit point in the second side of the junction;
- (h) inserting the second pointed end of the suture into the tissue at one side of the junction;
- (i) pushing the second end of the suture through the tissue until the second end of the suture extends out of the tissue at an exit point in the face of the tissue below the surface of the tissue at the one side of the junction;
- (j) gripping the second end of the suture and pulling the second end out of the tissue for drawing the second portion of the suture through the tissue until the second axial location is at the point of insertion of the second end of the suture and leaving a length of the second portion of the suture in the tissue between the point of insertion in the one side of the junction and the exit point in the face of the junction at the one side of the junction;
- (k) inserting the second end of the suture into the face of the tissue below the surface of the tissue at the other side of the junction;
- (l) pushing the second end of the suture through the tissue until the second end of the suture extends out of the tissue at an exit point on the other side of the junction longitudinally spaced in a second direction from the point of insertion of the second end of the suture at the one side of the junction; and
- (m) gripping the second end of the suture and pulling the second end out of the tissue for drawing the second portion of the suture through the tissue while bringing the sides of the junction together to the closed position along the second portion of the suture in the tissue and leaving a length of the second portion of the suture in the

tissue between the point of insertion in the one side of the junction and the exit point in the other side of the junction.

Claim 4 (withdrawn): A method for joining and holding portions of a stomach to each other as recited in claim 3, wherein the initial point of insertion of the first pointed end of the suture is laterally spaced from the face of the junction at the first side of the junction.

Claim 5 (withdrawn): A method for joining and holding portions of a stomach to each other as recited in claim 3, wherein the initial point of insertion of the first pointed end of the suture is into the face of the junction below the surface of the tissue at the first side of the junction.

Claim 6 (withdrawn): A method for joining and holding portions of a stomach to each other as recited in claim 3, wherein the steps of pushing the ends of the suture through the tissue comprise pushing the suture along a curvilinear path.

Claim 7 (withdrawn): A method for joining and holding portions of a stomach to each other as recited in claim 3, wherein the steps of pushing the ends of the suture comprise pushing the suture along a straight path.

Claim 8 (withdrawn): A method for joining and holding portions of a stomach to each other in the performance of a Nissen fundoplication procedure, the procedure requiring grasping the fundus of the stomach at a proximal location and pulling the fundus around the esophagus, wrapping the fundus around the esophagus one time and attaching the proximal stomach to an apposing portion of the stomach, the attachment made using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) gripping the proximal stomach and wrapping the fundus around the esophagus until the proximal stomach contacts an apposing portion of stomach and forms a junction of the proximal and the apposing stomach tissues;

- (b) inserting the first pointed end of the suture into the stomach tissue below the surface of the stomach tissue at a first face of the junction;
- (c) pushing the first end of the suture through the stomach tissue along a curvilinear path until the first end of the suture extends from the stomach tissue at an exit point in the first face of the junction longitudinally spaced in a first direction from the insertion point in the first face of the junction;
- (d) gripping the first pointed end of the suture and pulling the first end out of the stomach tissue for drawing the first portion of the suture through the stomach tissue until the second axial location is at the point of insertion of the first end of the suture in the first face of the junction and leaving a length of the first portion of the suture in the stomach tissue of the junction;
- (e) inserting the first pointed end of the suture at a point below the surface of the stomach tissue in a second face of the junction;
- (f) pushing the first end of the suture through the stomach tissue along a curvilinear path until the first end of the suture extends from the stomach tissue at an exit point in the second face of the junction below the surface of the stomach tissue and longitudinally spaced in the first direction from the insertion point in the second face of the junction;
- (g) repeating steps (b) through (f) for advancing longitudinally along the junction in the first direction as necessary to one end of the junction;
- (h) inserting the second pointed end of the suture into the stomach tissue of the second face of the junction below the surface of the stomach tissue and adjacent the initial point of insertion of the first end in the first face of the junction;
- (i) pushing the second end of the suture through the stomach tissue along a curvilinear path until the second end of the suture extends from the stomach tissue at an exit point below the surface of the stomach tissue in the second face of the junction and longitudinally spaced in a second direction from the point of insertion in the second face of the junction;
- (j) gripping the second pointed end of the suture and pulling the second end out of the stomach tissue for drawing the second portion of the suture through the stomach tissue until the second axial location is at the point of insertion of the second pointed end in the second face of the junction and leaving a length of the second portion of the suture in the stomach tissue of the junction;
- (k) inserting the second pointed end of the suture at a point in the first face of the junction below the surface of the stomach tissue;

(l) pushing the second end of the suture through the stomach tissue along a curvilinear path until the second end of the suture extends from the stomach tissue at an exit point in the first face of the junction below the surface of the stomach tissue and longitudinally spaced in the second direction from the point of insertion of the second end of the suture in the first face of the junction; and

(m) repeating steps (h) through (l) for advancing longitudinally along the junction in the second direction to the other end of the junction.

Claim 9 (withdrawn): A method for joining and holding portions of a stomach to each other as recited in claim 8, wherein the initial point of insertion of the first pointed end of the suture is adjacent an end of the junction and the first direction and second direction are the same direction.

Claim 10 (withdrawn): A method for joining and holding portions of a stomach to each other as recited in claim 8, wherein initial point of insertion of the first pointed end of the suture is longitudinally spaced from and between the ends of the junction and the first direction and second direction are opposite directions.

Claim 11 (withdrawn): A method for laparoscopically inserting a suture in a surgical procedure, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, and using a laparoscopic insertion device including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

(a) inserting the first pointed end of the suture and the leading end of the laparoscopic insertion device through the skin, and then through the fat, fascia, muscle, and peritoneum into the abdominal cavity;

(b) inserting the first end of the suture and leading end of the insertion device into tissue in the abdominal cavity at an entry point and pushing the first end of the suture and leading end of the insertion device into the tissue in the abdominal cavity; and

- (c) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place.

Claim 12 (withdrawn): A method for laparoscopically inserting a suture in a surgical procedure as recited in claim 11, wherein the procedure comprises stabilizing a bowel structure in position in preparation for additional procedures such as a laparoscopic anastomosis and the tissue in the abdominal cavity into which the suture is inserted is bowel tissue, and further comprising the steps of:

- (a) gripping and positioning the bowel structure in a location for stabilization;
and
- (b) leaving the inserted suture in place in the bowel tissue and the abdominal wall.

Claim 13 (withdrawn): A method for laparoscopically inserting a suture in a surgical procedure as recited in claim 11, wherein the procedure comprises a closure of a wound resulting from a cystostomy, the tissue into which the suture is inserted is urinary bladder muscularis, the entry point in the muscularis tissue is spaced from and on one side of the wound, and the first end of the suture and leading end of the insertion device are pushed through the tissue until the first end of the suture and the leading end of the insertion device extend out of the tissue at the wound, and further comprising the steps of:

- (a) inserting the first pointed end of the suture and the leading end of the insertion device through an opposing side of the wound;
- (b) pushing the first end of the suture and leading end of the insertion device through the tissue until the second axial location is proximate to a central to the point of the wound; and
- (c) advancing the tissue on the two sides of the lesion together as necessary to close the wound.

Claim 14 (withdrawn): A method for performing an anastomosis of the liver bile duct to a bowel structure, the bile duct having one end connected to the liver and a free end after having been severed, and the bowel structure having an opening in its wall made to receive the annular free end of the bile duct, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is

less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, and using an insertion device including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

- (a) placing the free end of the bile duct in contact with the opening in the bowel structure, forming a junction at the annular contact area between the bile duct tissue and the bowel structure tissue;
- (b) inserting the first pointed end of the suture and the leading end of the insertion device into the tissue on one side of the junction;
- (c) pushing the first end of the suture and leading end of the insertion device through the tissue on one side of the junction, through the junction, and penetrating tissue on the other side of the junction;
- (d) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place in both the bile duct tissue and the bowel structure tissue;
- (e) repeating steps (b) through (d) with additional sutures around the junction as necessary to provide an anastomotic seal at the junction.

Claim 15 (withdrawn): A method for performing an anastomosis of the liver bile duct to a bowel structure, the bile duct having one end connected to the liver and a free end after having been severed, and the bowel structure having an opening in its wall made to receive the annular free end of the bile duct, the bile duct comprising one of a first tissue and a second tissue, and the bowel tissue comprising the other of the first tissue and second tissue, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

(a) placing the free end of the bile duct in contact with the opening in the bowel structure, forming a junction at the annular contact area between the bile duct tissue and the bowel structure tissue;

(b) inserting the first pointed end of the suture into the first tissue at a point spaced from the junction;

(c) pushing the first end of the suture through the first tissue until the first end of the suture extends out of the first tissue at an exit point and penetrating the second tissue at a face of the junction until the first end of the suture extends out of the second tissue at an exit point spaced from the junction and spaced in a first direction along the circumference of the junction from the point of insertion of the first end of the suture in the first tissue;

(d) gripping the first end of the suture and pulling the first end out of the second tissue for drawing the first portion of the suture through the first tissue and the second tissue while bringing the first tissue and the second tissue together to a closed position along the first portion of the suture until the second axial location is at the point of insertion of the first end of the suture at the one side of the first tissue and leaving a length of the first portion of the suture in the first tissue and the second tissue between the point of insertion and the exit point;

(e) inserting the first end of the suture into the second tissue at the exit point of the first end;

(f) pushing the first end of the suture through the second tissue until the first end of the suture extends out of the second tissue at an exit point in the face of the junction and penetrating the first tissue until the first end of the suture extends out of the first tissue at an exit point spaced from the junction and spaced along the circumference of the junction in the first direction from the immediately preceding point of insertion of the first end of the suture in the first tissue;

(g) gripping the first end of the suture and pulling the first end out of the first tissue for drawing the first portion of the suture through the second tissue while bringing the first tissue and the second tissue together to a closed position along the first portion of the suture and leaving a length of the first portion of the suture in the periphery between the point of insertion and the exit point;

(h) repeating steps (b) through (g) as necessary for advancing around the circumference of the junction along the second tissue in the first direction;

- (i) inserting the second end of the suture into the first tissue at the insertion point of the first end;
- (j) pushing the second end of the suture through the first tissue until the second end of the suture extends out of the first tissue at an exit point and penetrating the second tissue at a face of the junction until the second end of the suture extends out of the second tissue at an exit point spaced from the junction and spaced along the circumference of the junction in the second direction from the point of insertion of the second end of the suture in the first tissue; and
- (k) gripping the second end of the suture and pulling the second end out of the second tissue for drawing the second portion of the suture through the tissue while bringing the first tissue and the second tissue together to the closed position along the second portion of the suture and leaving a length of the second portion of the suture in the first tissue and the second tissue between the point of insertion and the exit point.
- (l) inserting the second pointed end of the suture into the second tissue at the exit point of the second end;
- (m) pushing the second end of the suture through the second tissue until the second end of the suture extends out of the second tissue at an exit point in the face of the junction and penetrating the first tissue until the second end of the suture extends out of the first tissue at an exit point spaced from the junction and spaced along the circumference of the junction in a second direction from the point of insertion of the second end of the suture;
- (n) gripping the second pointed end of the suture and pulling the second end out of the first tissue for drawing the second portion of the suture through the first tissue and second tissue while bringing the first tissue and the second tissue together to a closed position along the second portion of the suture until the second axial location is at the point of insertion of the first end of the suture at the one side of the junction and leaving a length of the second portion of the suture in the first tissue and the second tissue between the point of insertion and the exit point; and
- (o) repeating steps (i) through (n) around the junction as necessary to provide an anastomotic seal at the junction.

Claim 16 (withdrawn): A method for tying off an appendiceal stump resulting from the performance of an appendectomy, the appendix extending from the cecum of the large intestine and having a base with a circumference at the juncture of the appendix and the cecum, using a barbed suture including an elongated body, first and second sharp pointed

distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture into tissue of the cecum proximate to the appendix base;
- (b) pushing the first end of the suture around the circumference of the base in one direction for at least one half of the of the circumference of the base until extending through an exit point in the tissue;
- (c) inserting the second pointed end of the suture into tissue of the cecum proximate to the entry point of the first end;
- (d) pushing the second end of the suture along the circumference of the base in the other direction for at least one half of the of the circumference of the base until extending through an exit point in the tissue;
- (e) excising the appendix, leaving the appendiceal stump; and
- (f) gripping and pulling the ends of the suture, causing the suture to tighten around the appendiceal stump.

Claim 17 (withdrawn): The method of claim 16, further comprising the step of inverting the appendiceal stump such that the stump is disposed within the cecum.

Claim 18 (withdrawn): A method for joining and holding closed the muscle layers that define the orifice of a Zenker's Diverticulum, the Zenker's Diverticulum including a sac extending from a proximal location of the esophagus near the pharynx, the sac having walls including a muscle layer common to the proximal esophagus, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on

the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, and using an endoscopic insertion device that passes through the mouth, throat, and pharynx, including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture and the leading end of the endoscopic insertion device through an entry point in the esophageal muscle between the pharynx and the orifice, and spaced from the orifice on the side of the orifice towards the mouth;
- (b) pushing the first end of the suture and leading end of the insertion device through the muscle until the first end of the suture and the leading end of the insertion device extend out of the muscle at the orifice of the sac;
- (c) inserting the first pointed end of the suture and the leading end of the endoscopic insertion device through an opposing side of the orifice;
- (d) pushing the first end of the suture and leading end of the insertion device through the muscle until the second axial location is proximate to a central point of the orifice;
- (e) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place;
- (f) optionally repeating steps (a) through (e) as desired with additional sutures; and
- (g) advancing the muscle on the two sides of the orifice together as necessary to close the orifice.

Claim 19 (withdrawn): A method for joining and holding closed ulcerative lesions or post-procedural tissue defects on an interior surface of a viscus, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the

second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, and using an endoscopic insertion device, including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture and the leading end of the endoscopic insertion device through an entry point in the tissue spaced from and on one side of the lesion;
- (b) pushing the first end of the suture and leading end of the insertion device through the tissue until the first end of the suture and the leading end of the insertion device extend out of the tissue at the lesion;
- (c) inserting the first pointed end of the suture and the leading end of the endoscopic insertion device through an opposing side of the lesion;
- (d) pushing the first end of the suture and leading end of the insertion device through the tissue until the second axial location is proximate to a central to the point of the lesion;
- (e) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place; and
- (f) optionally repeating steps (a) through (e) as desired with additional sutures;
- (g) advancing the tissue on the two sides of the lesion together as necessary to close the lesion.

Claim 20 (withdrawn): A method for joining and holding closed a wound in urinary bladder muscularis tissue to allow tissue healing and regrowth together of the sides of the wound, or reconfiguration in vivo, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture into the tissue below the surface of the tissue at a first face of the wound at an initial point;
- (b) pushing the first end of the suture through the tissue along a curvilinear path until the first end of the suture extends from the tissue at an exit point in the first face of the wound and longitudinally spaced in a first direction from the insertion point in the first face of the wound;
- (c) gripping the first pointed end of the suture and pulling the first end out of the tissue for drawing the first portion of the suture through the tissue until the second axial location is at the point of insertion of the first end of the suture in the first face of the wound and leaving a length of the first portion of the suture in the tissue;
- (d) inserting the first pointed end of the suture at a point below the surface of the tissue in a second face of the wound;
- (e) pushing the first end of the suture through the tissue along a curvilinear path until the first end of the suture extends from the tissue at an exit point in the second face of the wound below the surface of the tissue and longitudinally spaced in the first direction from the insertion point in the second face of the wound;
- (f) repeating steps (a) through (e) for advancing longitudinally along the wound in the first direction as necessary to one end of the wound;
- (g) inserting the second pointed end of the suture into the tissue of the second face of the wound below the surface of the tissue and adjacent the initial point of insertion of the first end in the first face of the wound;
- (h) pushing the second end of the suture through the tissue along a curvilinear path until the second end of the suture extends from the tissue at an exit point below the surface of the tissue in the second face of the wound and longitudinally spaced in a second direction from the point of insertion in the second face of the wound;
- (i) gripping the second pointed end of the suture and pulling the second end out of the tissue for drawing the second portion of the suture through the tissue until the second axial location is at the point of insertion of the second pointed end in the second face of the wound and leaving a length of the second portion of the suture in the tissue;
- (j) inserting the second pointed end of the suture at a point in the first face of the wound below the surface of the tissue;

- (k) pushing the second end of the suture through the tissue along a curvilinear path until the second end of the suture extends from the tissue at an exit point in the first face of the wound below the surface of the tissue and longitudinally spaced in the second direction from the point of insertion of the second end of the suture in the first face of the wound; and
- (l) repeating steps (g) through (k) for advancing longitudinally along the wound in the second direction to the other end of the wound.

Claim 21 (withdrawn): A method for joining and holding closed a wound in urinary bladder muscularis tissue as recited in claim 20, wherein the initial point of insertion of the first pointed end of the suture is adjacent an end of the junction and the first direction and second direction are the same direction.

Claim 22 (withdrawn): A method for joining and holding closed a wound in urinary bladder muscularis tissue as recited in claim 20, wherein the initial point of insertion of the first pointed end of the suture is longitudinally spaced from and between the ends of the junction and the first direction and second direction are opposite directions.

Claim 23 (withdrawn): A method for joining and holding closed a wound in urinary bladder muscularis tissue to allow tissue healing and regrowth together of the sides of the wound, or reconfiguration in vivo, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture into the muscularis tissue below the surface of the muscularis tissue at a first face of the wound at an initial point;
- (b) pushing the first end of the suture through the muscularis tissue along a curvilinear path until the first end of the suture extends from the muscularis tissue at an exit point in the first face of the wound longitudinally spaced in a first direction from the insertion point in the first face of the wound;
- (c) gripping the first pointed end of the suture and pulling the first end out of the muscularis tissue for drawing the first portion of the suture through the

muscularis tissue until the second axial location is at the point of insertion of the first end of the suture in the first face of the wound and leaving a length of the first portion of the suture in the muscularis tissue of the wound;

(d) inserting the first pointed end of the suture at a point below the surface of the muscularis tissue in a second face of the wound;

(e) pushing the first end of the suture through the muscularis tissue along a curvilinear path until the first end of the suture extends from the muscularis tissue at an exit point in the second face of the wound below the surface of the muscularis tissue and longitudinally spaced in the first direction from the insertion point in the second face of the wound;

(f) inserting the first end of the suture at a point in the first face of the wound below the surface of the muscularis tissue;

(g) repeating steps (b) through (f) for advancing longitudinally along the wound in the first direction as necessary to one end of the wound;

(h) inserting the second pointed end of the suture into the muscularis tissue of the second face of the wound below the surface of the muscularis tissue and adjacent the initial point of insertion of the first end in the first face of the wound;

(i) pushing the second end of the suture through the muscularis tissue along a curvilinear path until the second end of the suture extends from the muscularis tissue at an exit point below the surface of the muscularis tissue in the second face of the wound and longitudinally spaced in a second direction from the point of insertion in the second face of the wound;

(j) gripping the second pointed end of the suture and pulling the second end out of the muscularis tissue for drawing the second portion of the suture through the muscularis tissue until the second axial location is at the point of insertion of the second needle in the second face of the wound and leaving a length of the second portion of the suture in the muscularis tissue of the wound;

(k) inserting the second pointed end of the suture at a point in the first face of the wound below the surface of the muscularis tissue;

(l) pushing the second end of the suture through the muscularis tissue along a curvilinear path until the second end of the suture extends from the muscularis tissue at an exit point in the first face of the wound below the surface of the muscularis tissue and longitudinally spaced in the second direction from the point of insertion of the second end of the suture in the first face of the wound;

(m) inserting the second pointed end of the suture at a point in the first face of the wound below the surface of the muscularis tissue; and

(n) repeating steps (i) through (m) for advancing longitudinally along the wound in the second direction to the other end of the wound.

Claim 24 (withdrawn): A method for joining and holding closed a wound in urinary bladder muscularis tissue as recited in claim 23, wherein the initial point is adjacent an end of the junction and the first direction and second direction are the same direction.

Claim 25 (withdrawn): A method for joining and holding closed a wound in urinary bladder muscularis tissue as recited in claim 23, wherein the initial point is longitudinally spaced from and between the ends of the junction and the first direction and second direction are opposite directions.

Claim 26 (withdrawn): A method for joining a foreign element and bodily tissue, the foreign element having a periphery, the bodily tissue having a fibrous tissue ring with a face of the fibrous tissue ring defining an opening and apposing a face of the periphery, with both the foreign element and the tissue comprising matter, and holding closed a junction between the element and the tissue to allow tissue healing and regrowth, or reconfiguration in vivo, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

(a) inserting the first pointed end of the suture into matter on a first side of the junction at a point radially spaced from the junction;

(b) pushing the first end of the suture through the matter on the first side until the first end of the suture extends out of the first side matter at an exit point and penetrating the face of the matter on the second side of the junction until the first end of the suture extends out of the second side matter at an exit point radially spaced from the junction and spaced along the junction circumference in a first direction from the point of insertion of the first end of the suture in the first side matter;

(c) gripping the first end of the suture and pulling the first end out of the second side matter for drawing the first portion of the suture through the first and second side matter while bringing the first and second side matter together to a closed position along the first portion of the suture until the second axial location is at the point of insertion of the first end of the suture in the first side matter and leaving a length of the first portion of the suture in the first and second side matter between the point of insertion and the exit point;

(d) inserting the first end of the suture into the second side matter at the exit point of the first end;

(e) pushing the first end of the suture through the second side matter until the first end of the suture extends out of the second side matter at an exit point in the face of the second side matter and penetrating the first side matter until the first end of the suture extends out of the first side matter at an exit point radially spaced from the junction and spaced along the junction circumference in the first direction from the point of insertion of the first end of the suture in the first side matter;

(f) gripping the first end of the suture and pulling the first end out of the first side matter for drawing the first portion of the suture through the first and second side matter while bringing the first and second side matter together to a closed position along the first portion of the suture and leaving a length of the first portion of the suture in the first side matter between the point of insertion and the exit point;

(g) repeating steps (a) through (f), with each repetition advancing along the junction circumference in the first direction;

(h) inserting the second end of the suture into the first side matter at the insertion point of the first end;

(i) pushing the second end of the suture through the first side matter until the second end of the suture extends out of the first side matter at an exit point and penetrating the face of the second side matter until the second end of the suture extends out of the second side matter at an exit point radially spaced from the junction and spaced along the junction circumference in the second direction from the point of insertion of the second end of the suture on the first side matter; and

(j) gripping the second end of the suture and pulling the second end out of the second side matter for drawing the second portion of the suture through the second side matter while bringing the first side matter and the second side matter together to the closed position along the second portion of the suture and leaving a length of the second portion of the suture in the first and second side matter between the point of insertion and the exit point;

(k) inserting the second pointed end of the suture into the second side matter at the exit point of the second end;

(l) pushing the second end of the suture through the second side matter until the second end of the suture extends out of the second side matter at an exit point in the face of the second side matter and penetrating the first side matter until the second end of the suture extends out of the first side matter at an exit point radially spaced from the junction and spaced along the junction circumference in a second direction from the point of insertion of the second end of the suture;

(m) gripping the second pointed end of the suture and pulling the second end out of the periphery for drawing the second portion of the suture through the first and second side matter while bringing the first and second side matter together to a closed position along the second portion of the suture until the second axial location is at the point of insertion of the first end of the suture in the second side matter and leaving a length of the second portion of the suture in the first and second side matter between the point of insertion and the exit point; and

(n) repeating steps (h) through (m), with each repetition advancing along the junction circumference in the second direction.

Claim 27 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 26, wherein the foreign element is a bioprosthetic heart valve and the tissue is heart tissue.

Claim 28 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 26, wherein the foreign element is a mechanical prosthetic heart valve and the tissue is heart tissue.

Claim 29 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 26, wherein the foreign element is a bioprosthetic patch for cardiac septal defects and the tissue is heart tissue.

Claim 30 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 26, further comprising the step of continuing to advance the first portion and the second portion of the sutures at least until the entire periphery is joined to the tissue.

Claim 31 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 26, further comprising the step of continuing to advance the first portion

and the second portion of the sutures until the first and second portion overlap for at least one quarter of the periphery.

Claim 32 (withdrawn): A method for joining a foreign element and bodily tissue, the foreign element having a periphery, the bodily tissue having a fibrous tissue ring with a face of the fibrous tissue ring defining an opening and apposing a face of the periphery, with both the foreign element and the tissue comprising matter, and holding closed a junction between the element and the tissue to allow tissue healing and regrowth, or reconfiguration in vivo, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture into the first side matter below the surface of the first side matter at a first face of the junction;
- (b) pushing the first end of the suture through the first side matter along a curvilinear path until the first end of the suture extends from the first side matter at an exit point in the first face of the junction below the surface of the first side matter and spaced along the junction circumference in a first direction from the insertion point in the first face of the junction;
- (c) gripping the first pointed end of the suture and pulling the first end out of the first side matter for drawing the first portion of the suture through the first side matter until the second axial location is at the point of insertion of the first end of the suture in the first face of the junction and leaving a length of the first portion of the suture in the first side matter;
- (d) inserting the first pointed end of the suture at a point below the surface of the second side matter in a second face of the junction;
- (e) pushing the first end of the suture through the second side matter along a curvilinear path until the first end of the suture extends from the second side matter at an exit point in the second face of the junction below the surface of the second side matter and spaced along the junction circumference in the first direction from the insertion point in the second face of the junction;

- (f) repeating steps (a) through (e) for advancing longitudinally along the junction circumference in the first direction;
- (g) inserting the second pointed end of the suture into the second side matter of the second face of the junction below the surface of the second side matter and adjacent the initial point of insertion of the first end in the first face of the wound;
- (h) pushing the second end of the suture through the second side matter along a curvilinear path until the second end of the suture extends from the second side matter at an exit point below the surface of the second side matter in the second face of the junction and spaced along the junction circumference in a second direction from the point of insertion in the second face of the junction;
- (i) gripping the second pointed end of the suture and pulling the second end out of the second side matter for drawing the second portion of the suture through the second side matter until the second axial location is at the point of insertion of the second pointed end in the second face of the junction and leaving a length of the second portion of the suture in the second side matter;
- (j) inserting the second pointed end of the suture at a point in the first face of the wound below the surface of the first side matter;
- (k) pushing the second end of the suture through the first side matter along a curvilinear path until the second end of the suture extends from the first side matter at an exit point in the first face of the junction below the surface of the first side matter and spaced along the junction circumference in the second direction from the point of insertion of the second end of the suture in the first face of the junction; and
- (l) repeating steps (g) through (k) for advancing longitudinally along the wound in the second direction to the other end of the wound.

Claim 33 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 32, wherein the foreign element is a bioprosthetic heart valve and the tissue is heart tissue.

Claim 34 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 32, wherein the foreign element is a mechanical prosthetic heart valve and the tissue is heart tissue.

Claim 35 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 32, wherein the foreign element is a bioprosthetic patch for cardiac septal defects and the tissue is heart tissue.

Claim 36 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 32, further comprising the step of continuing to advance the first portion and the second portion of the sutures at least until the entire periphery is joined to the tissue.

Claim 37 (withdrawn): A method for joining a foreign element and bodily tissue as recited in claim 32, further comprising the step of continuing to advance the first portion and the second portion of the sutures until the first and second portion overlap for at least one quarter of the periphery.

Claim 38 (withdrawn): A method of mounting a device to bodily tissue, the device including at least one eyelet for securing the device and through which a suture may pass, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) placing the device in a desired position;
- (b) threading a suture through the at least one eyelet;
- (c) inserting the first pointed end of the suture into tissue;
- (d) pushing the first end of the suture through the tissue until the first end of the suture extends out of the tissue at an exit point;
- (e) gripping the first end of the suture and pulling the first end out of the tissue while drawing the first portion of the suture through the tissue, leaving a portion of the suture between the first and second axial locations out of the tissue and leaving a length of the first portion of the suture in the tissue between the point of insertion and exit point of the first end;
- (f) inserting the second pointed end of the suture into tissue;
- (g) pushing the second end of the suture through the tissue until the second end of the suture extends out of the tissue at an exit point, leaving a portion of the suture between the first and second axial locations out of the tissue; and

(h) gripping the second end of the suture and pulling the second end out of the tissue while drawing the second portion of the suture through the tissue until the device is secured and leaving a length of the second portion of the suture in the tissue between the point of insertion and exit point of the second end;

wherein the first and second portions of the suture extend in the tissue in generally opposing directions and cause the suture to resist displacement of the device.

Claim 39 (withdrawn): A method for mounting a device to bodily tissue as recited in claim 38, wherein the device is a catheter.

Claim 40 (withdrawn): A method for mounting a device to bodily tissue as recited in claim 38, wherein the device is a tumor monitor.

Claim 41 (withdrawn): A method for mounting a device to bodily tissue as recited in claim 38, wherein the device is an electrode of a cardiac pacemaker.

Claim 42 (withdrawn): A method for mounting a device to bodily tissue as recited in claim 38, wherein the bodily tissue to which the device is mounted is an internal organ.

Claim 43 (withdrawn): A method for mounting a device to bodily tissue as recited in claim 38, wherein the bodily tissue to which the device is mounted includes the skin.

Claim 44 (withdrawn): A method for mounting a device to bodily tissue as recited in claim 38, wherein at least one of the first and second sutures is inserted in a curvilinear path.

Claim 45 (original): A method of performing a cosmetic surgery procedure using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

(a) inserting the first pointed end at an insertion point on the surface of a person's body;

- (b) pushing the first end of the suture through soft tissue until the first end of the suture extends out of the soft tissue at an exit point;
- (c) gripping and pulling the first end of the suture to draw the first portion of the suture through the soft tissue until the second axial location is proximate to the point of insertion of the first end of the suture and leaving a length of the first portion of the suture in the soft tissue between the point of insertion and exit point of the first end;
- (d) inserting the second pointed end of the suture at the point of insertion of the first end;
- (e) pushing the second end of the suture through soft tissue until the second end of the suture extends out of the soft tissue at an exit point;
- (f) gripping and pulling the second end of the suture to draw the second portion of the suture through the soft tissue until the second axial location is proximate to the point of insertion of the second end of the suture and leaving a length of the second portion of the suture in the soft tissue between the point of insertion and exit point of the second end; and
- (g) manually grouping and advancing the soft tissue along at least one portion of the suture to provide a desired amount of lift.

Claim 46 (original): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a facelift and the insertion point is approximately at the temporal hairline;
- (b) the first end of the suture is pushed through subepidermal tissue to the exit point on the scalp;
- (c) the second end of the suture is pushed through subepidermal tissue, the superficial muscular aponeurotic system, or combinations thereof, to the exit point proximate to the nasolabial fold; and
- (d) tissue is manually grouped and advanced along the second portion of the suture to provide the desired amount of lift.

Claim 47 (original): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a browlift and the insertion point is on a person's face above the brow line;

- (b) the first end of the suture is pushed through subepidermal tissue underneath the scalp and the exit point of the first end of the suture is on the scalp;
- (c) the second end of the suture is pushed through subepidermal tissue and the exit point of the second end of the suture is proximate to the brow; and
- (d) the tissue is manually grouped and advanced along the second portion of the suture to provide the desired amount of lift.

Claim 48 (original): A method of performing a cosmetic surgery procedure as recited in claim 47, wherein the insertion point is approximately at the frontal hairline.

Claim 49 (original): A method of performing a cosmetic surgery procedure as recited in claim 47, wherein the insertion point is approximately at the midpoint between the brow and the frontal hairline.

Claim 50 (original): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a browlift and the insertion point is on a person's face above the brow line;
- (b) the first end of the suture is pushed through subepidermal tissue and the exit point of the first end of the suture is proximate to the brow;
- (c) the second end of the suture is pushed through subepidermal tissue and the exit point of the second end of the suture is proximate to the brow and spaced from the exit point of the first end of the suture; and
- (d) the tissue is manually grouped and advanced along the first and second portions of the suture to provide the desired amount of lift.

Claim 51 (original): A method of performing a cosmetic surgery procedure as recited in claim 50, wherein the insertion point is approximately at the frontal hairline.

Claim 52 (original): A method of performing a cosmetic surgery procedure as recited in claim 50, wherein the insertion point is approximately at the midpoint between the brow and the frontal hairline.

Claim 53 (original): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a thigh lift and the insertion point is generally at the inguinal crease;
- (b) the first end of the suture is pushed cranially through subepidermal tissue until the first end of the suture extends out of the tissue; and
- (c) the second end of the suture is pushed caudally through subepidermal tissue until the second end of the suture extends out of the tissue on the thigh.

Claim 54 (original): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a breast lift and the insertion point is at the upper aspect of the breast curvature;
- (b) the first end of the suture is pushed through subcutaneous tissue, dermal tissue, and pectoralis muscle until extending out of the tissue at an exit point on the upper portion of the breast; and
- (c) the second end of the suture is pushed caudally through fibrous and fatty tissues until the second end of the suture extends out of the tissue at an exit point along the anterior aspect or the lower curvature of the breast.

Claim 55 (original): A method of performing a cosmetic surgery procedure using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, and using an insertion device including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture and the leading end of the insertion device at an insertion point;
- (b) pushing the first end of the suture and the leading end of the insertion device through tissue beneath the epidermis until reaching an endpoint;

- (c) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place; and
- (d) manually grouping and advancing the tissue along the first portion of the suture to provide the desired amount of lift.

Claim 56 (original): The method of performing a cosmetic surgery procedure as recited in claim 55, wherein:

- (a) the cosmetic surgery is a facelift;
- (b) the insertion point is in the scalp at a point distal from the temporal hairline;
- (c) the suture is pushed through the reticular dermis underneath the scalp; and
- (d) the first end of the suture then passes through the temporal hairline, penetrating the facial tissue selected from a group consisting of the reticular dermis, the superficial muscular aponeurotic system, and a combination thereof, extending to be proximate to the nasolobial fold.

Claim 57 (original): The method of performing a cosmetic surgery procedure as recited in claim 55, wherein:

- (a) the cosmetic surgery is a browlift;
- (b) the insertion point is in the scalp at a point distal from the frontal hairline; and
- (c) the suture is pushed through the reticular dermis underneath the scalp until the first end of the suture passes through the frontal hairline, extending to be proximate to the inferior aspect of the brow line.

Claim 58 (withdrawn): A method for joining and holding closed for healing and regrowth an axial wound in a blood vessel such as an artery or vein, using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction

opposite the direction of movement of the second end, and using an insertion device, including a tubular element in which the suture is initially disposed, the insertion device having leading and trailing ends with openings therein with the first end of the suture proximate to the leading end, the method comprising the steps of:

- (a) inserting the first pointed end of the suture and the leading end of the insertion device through an entry point in the tissue spaced from and on one side of the wound;
- (b) pushing the first end of the suture and leading end of the insertion device through the tissue until the first end of the suture and the leading end of the insertion device penetrate the blood vessel wall on one side of the wound, extend into the interior of the blood vessel, penetrate the blood vessel wall on the other side of the wound, and penetrate the tissue on the other side of the wound;
- (c) gripping and pulling the insertion device at the trailing end to remove the insertion device, leaving the suture in place; and
- (d) advancing the tissue on the two sides of the wound together as necessary to close the wound.

Claim 59 (withdrawn): A method for joining and holding closed for healing and regrowth an axial wound in a blood vessel as recited in claim 58, further comprising the step of pushing the first end of the suture and the leading end of the insertion device through the tissue until the second axial location is disposed outside the blood vessel wall on one side of the wound and the first axial location is disposed outside the blood vessel wall on the other side of the wound, whereby there are no barbs disposed in the interior of the blood vessel.

Claim 60 (new): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a facelift and the insertion point is approximately at the posterior mandibular angle;
- (b) the first end of the suture is pushed posteriorly through subepidermal tissue, the superficial aponeurotic system, or combinations thereof along a path approximately parallel to the mandibular border, exiting distally;
- (c) the second end of the suture is pushed anteriorly through subepidermal tissue, the superficial aponeurotic system, or combinations thereof along a path approximately parallel to the mandibular border, exiting distally;
- (d) tissue is manually grouped and advanced along the second portion of the suture to provide the desired amount of lift.

Claim 61 (new): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein:

- (a) the cosmetic surgery procedure is a neck lift and the insertion point is approximately at the upper sternomastoid muscle;
- (b) the first end of the suture is pushed posteriorly through subepidermal tissue, the superficial aponeurotic system, or combinations thereof along a path approximately parallel to the mandibular border, exiting distally;
- (c) the second end of the suture is pushed anteriorly through subepidermal tissue, the superficial aponeurotic system, or combinations thereof along a path approximately parallel to the mandibular border, exiting distally;
- (d) tissue is manually grouped and advanced along the second portion of the suture to provide the desired amount of lift.

Claim 62 (new): A method of performing a cosmetic surgery procedure as recited in claim 45, wherein the first and second sharp pointed distal ends are needles.

Claim 63 (new): A method of performing a cosmetic surgery procedure as recited in claim 46, wherein the first and second sharp pointed distal ends are needles.

Claim 64 (new): A method of performing a cosmetic surgery procedure as recited in claim 47, wherein the first and second sharp pointed distal ends are needles.

Claim 65 (new): A method of performing a cosmetic surgery procedure as recited in claim 48, wherein the first and second sharp pointed distal ends are needles.

Claim 66 (new): A method of performing a cosmetic surgery procedure as recited in claim 49, wherein the first and second sharp pointed distal ends are needles.

Claim 67 (new): A method of performing a cosmetic surgery procedure as recited in claim 50, wherein the first and second sharp pointed distal ends are needles.

Claim 68 (new): A method of performing a cosmetic surgery procedure as recited in claim 51, wherein the first and second sharp pointed distal ends are needles.

Claim 69 (new): A method of performing a cosmetic surgery procedure as recited in claim 52, wherein the first and second sharp pointed distal ends are needles.

Claim 70 (new): A method of performing a cosmetic surgery procedure as recited in claim 53, wherein the first and second sharp pointed distal ends are needles.

Claim 71 (new): A method of performing a cosmetic surgery procedure as recited in claim 54, wherein the first and second sharp pointed distal ends are needles.

Claim 72 (new): A method of performing a cosmetic surgery procedure as recited in claim 60, wherein the first and second sharp pointed distal ends are needles.

Claim 73 (new): A method of performing a cosmetic surgery procedure as recited in claim 61, wherein the first and second sharp pointed distal ends are needles.

Claim 74 (new): A method of performing a cosmetic surgery procedure as recited in claim 55, wherein the first sharp pointed distal end is a needle.

Claim 75 (new): A method of performing a cosmetic surgery procedure as recited in claim 56, wherein the first sharp pointed distal end is a needle.

Claim 76 (new): A method of performing a cosmetic surgery procedure as recited in claim 57, wherein the first sharp pointed distal end is a needle.

Claim 77 (new): A method of performing a cosmetic surgery procedure using a barbed suture including an elongated body, first and second sharp pointed distal ends for penetrating tissue, and a plurality of barbs extending from the periphery of the body, the barbs on a first portion of the body between the first end of the suture and a first axial location on the body for permitting movement of the suture through the tissue in a direction of movement of the first end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the first end, and the barbs on a second portion of the body between the second end of the suture and a second axial location on the body which is less than the distance from the second end to the first axial location permitting movement of the suture through the tissue in a direction of movement of the second end and preventing movement of the suture relative to the tissue in a direction opposite the direction of movement of the second end, the method comprising the steps of:

- (a) inserting the first pointed end at an insertion point on the surface of a person's body;
- (b) pushing the first end of the suture through subepidermal tissue until the first end of the suture extends out of the soft tissue at an exit point;
- (c) gripping and pulling the first end of the suture to draw the first portion of the suture through the subepidermal tissue until the second axial location is proximate to the point of insertion of the first end of the suture and leaving a length of the first portion of the suture in the subepidermal tissue between the point of insertion and exit point of the first end;

- (d) inserting the second pointed end of the suture at the point of insertion of the first end;
- (e) pushing the second end of the suture through subepidermal tissue until the second end of the suture extends out of the soft tissue at an exit point;
- (f) gripping and pulling the second end of the suture to draw the second portion of the suture through the subepidermal tissue until the second axial location is proximate to the point of insertion of the second end of the suture and leaving a length of the second portion of the suture in the subepidermal tissue between the point of insertion and exit point of the second end; and
- (g) manually grouping and advancing the subepidermal tissue along at least one portion of the suture to provide a desired amount of lift.

Claim 78 (new): A method of performing a cosmetic surgery procedure as recited in claim 77, wherein the first and second sharp pointed distal ends are needles.

REMARKS/ARGUMENTS

In the specification, paragraph [0118.1] is added to correct a minor informality of introducing the claims.

Claims 1-44, 58, and 59 are withdrawn as a result of an earlier restriction requirement. Original claims 45-57 remain in the application.

New claims 60 and 61, directed to a facelift and a neck lift, respectively, are added to more completely claim the invention as disclosed. Support for these new claims is provided at paragraph [0099] and Figure 49. The names of entry points and technical terms of art used in the claims are known to one of ordinary skill in the art and may be identified by the locations shown in Figure 49.

New claims 62-73, each directed to a method of performing a cosmetic surgery procedure, explicitly recite that the first and second sharp pointed distal ends of the barbed suture are needles. New claims 74-76, each directed to a method of performing a cosmetic surgery procedure, explicitly recite that the first sharp pointed distal end of the barbed suture is a needle. Support for these amendments may be found at, for example, paragraph [0048], Figures 1 and 2, paragraph [0099], paragraph [0104], and paragraph [0105].

New claim 77 is directed to a method of performing a cosmetic surgery procedure, and recites pushing, gripping, and pulling the suture ends through subepidermal tissue, and leaving lengths of the suture in the subepidermal tissue. New claim 77 is otherwise similar to claim 45. Support for the recital of subepidermal tissue is found in paragraphs [0099], [0101], [0102], [0104], and [0105]. New claim 78, directed to a method of performing a cosmetic surgery procedure, explicitly recites that the first and second sharp pointed distal ends of the barbed suture are needles. Support for this amendment may be found at, for example, paragraph [0048], Figures 1 and 2, paragraph [0099], paragraph [0104], and paragraph [0105].

Applicants hereby request further examination and reconsideration of the application in view of the discussion below.

Claim Rejections – 35 USC § 102

Claims 45 and 46 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,931,455 to Buncke. Independent claim 45 is directed to a method for performing a cosmetic surgery procedure and claim 46, which depends from claim 45, is directed to a method for performing a facelift. The Examiner states that Buncke discloses a method of performing a cosmetic surgery procedure or a facelift, including inserting first and second ends of a barbed suture into a point of insertion on a person's body,

where the first and second ends extend out of soft (subepidermal) tissue at exit points, and where the barbed suture has an elongated body with first and second pointed distal ends and a plurality of barbs extending along the periphery of the body.

Applicants respectfully submit that claim 45 is not anticipated by Bunke because Bunke fails to disclose every element recited in claim 45. For example, Bunke does not disclose at least one additional step that is claimed by the Applicants in claim 45: "manually grouping and advancing the soft tissue along at least one portion of the suture to provide a desired amount of lift." This additional claimed step, not included in Bunke, overcomes the Examiner's novelty rejection.

As claim 46 depends from allowable claim 45 and claims additional features of the present invention, claim 46 is allowable for the same reasons as claim 45, discussed above. For example, claim 46 requires pushing the second end of the suture through subepidermal tissue, the superficial muscular aponeurotic system, or combinations thereof, and exiting the tissue proximate to the nasolobial fold. Neither Bunke's specification nor figures show this path. *See, e.g.*, Bunke Figure 12. Claim 46 is therefore not anticipated by Bunke.

For the foregoing reasons, the Applicants respectfully submit that the claimed cosmetic surgery and facelift procedures defined by claims 45 and 46 are not anticipated by Bunke. Reconsideration and withdrawal of the rejection and allowance of claims 45 and 46 are requested.

Claim Rejections – 35 USC § 103

1. Claims 46-54

Initially, it should be noted that claims 46-54 all depend directly or indirectly from claim 45 and as such are believed to be allowable for the reasons discussed above. Nonetheless, for completeness, Applicants will address the rejection of claims 46-54 below.

The Examiner rejected claims 46-54 based on 35 U.S.C. § 103(a) obviousness as unpatentable over Bunke in view of U.S. Patent No. 5,217,494 to Coggins et al. Claims 47-52 are directed to methods for performing a browlift. Claim 53 is directed to a method for performing a thigh lift, and claim 54 is directed to a method for performing a breast lift.

The Examiner states that Bunke discloses Applicants' invention substantially as claimed, but does not disclose cosmetic procedures including a browlift, a thigh lift, and a breast lift, where the barbed suture is inserted into subepidermal tissues to provide a desired amount of lift. The Examiner further states that Coggins et al. teach a subepidermal implant and method for lifting loose or sagging tissue in cosmetic surgical procedures, such as a facelift, suspension of the buttock, suspension of the eyelid, a thigh

lift, and a breast lift. The Examiner states that “it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the invention of Buncke in cosmetic procedures, such as a browlift (which is actually a type of face lift), a thigh lift, and a breast lift. As in a face lift, Buncke’s barbed suture and method, which are analogous to the prosthesis and method of Coggins et al., would also provide an effective means for lifting or suspending other sagging tissues.”

Coggins et al. discloses an implantable prosthesis including a band and a “paddle” at one end of the band. Col. 2, lines 26-37. The prosthesis is implanted and each end is sutured in place. Col. 5, lines 17-23. The band has a coating that resists attachment of tissue, such as silicone; it is undesirable for tissue to attach to the band. Col. 2, lines 61-64. It is desirable for tissue to attach to the paddle, and tissue regrowth around the paddle after implantation is necessary to anchor the paddle. Col. 2, line 67 to col. 3, line 5. Once the tissue regrowth has occurred, estimated at one and one half months, then another incision is made to allow application of force to the band to move the skin into the desired position. Col. 5, lines 51-60. Then the end of the band opposite the paddle is anchored to solid material, such as bone or fascia. Col. 4, lines 53-60.

Applicants respectfully submit that the Examiner has failed to make a *prima facie* case of obviousness created by the combination of Buncke and Coggins et al. because at least two of three basic criteria are not met: there is no suggestion or motivation to combine the references and the references do not teach or suggest all of the claim limitations. *See* MPEP § 2143.

First, there is no suggestion or motivation to combine Buncke and Coggins et al. MPEP § 2143.01. Although Coggins et al. discloses use of its prosthesis in the cosmetic surgery procedures as stated by the Examiner, there is no suggestion of the desirability of the combination with a suture as in Buncke. The prior art must suggest the desirability of the combination, not just serve to show that the references can be combined or modified. The design and principal of operation of Buncke are too different from Coggins et al. to suggest the desirability of the combination. For example, Buncke is inserted with needles with little invasiveness, and functions immediately. On the other hand, Coggins et al. is inserted through several incisions made at various times, requires time for tissue regrowth to function, and is relatively bulky. Further, Buncke requires resistance in tissue along the suture’s length, while Coggins et al. requires anchoring at each end. Coggins et al. teaches away from resistance in tissue along its band, instead requiring a coating that prevents adhesion of tissue.

Second, the cited references must teach or suggest all of the claim limitations. As previously noted with respect to novelty, manual grouping and advancing of tissue along the suture is an additional step in Applicants’ claims 46-54 that is not disclosed in Buncke; nor is it disclosed in Coggins et al. In addition, there are other features recited in claims 46-54 that are not disclosed in Buncke or Coggins et al. For example, Applicants’ claim 46 requires that “the second end of the suture is pushed through subepidermal tissue, the superficial muscular aponeurotic system, or combinations thereof, to the exit

point proximate to the nasolobial fold.” The suture path of claim 50 is not taught by the cited references, either, with one embodiment being shown in Applicants’ Figure 49, element 422 (inverted “V” shape for a browlift). Nor are the paths of the suture of the thigh lift and breast lift of claims 53 and 54 disclosed in Buncke or Coggins et al.

Applicants respectfully submit that the claimed cosmetic surgery procedures defined by claims 46-54 are nonobvious over Buncke in view of Coggins et al.

2. *Claims 55 and 56*

The Examiner rejected claims 55 and 56 based on 35 U.S.C. § 103(a) obviousness as unpatentable over Buncke in view of U.S. Patent No. 4,493,323 to Albright et al. Independent claim 55 is directed to a method for performing a cosmetic surgery procedure using an insertion device, and claim 56, depending from claim 55, is directed to a method for performing a facelift.

The Examiner states that Buncke discloses the invention substantially as claimed, but does not disclose the application of an insertion device with the suture. The Examiner cites Albright et al. as teaching the application of an insertion device for the insertion of a suture through tissue being joined. The Examiner stated that it “would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Albright et al., to apply a suture insertion device in the method of Buncke, and that the insertion device would provide a means to insert and guide a suture through tissue at precise locations. Such an insertion device would provide means to insert and guide a suture through tissue at precise locations.”

Albright et al. includes an ovular sleeve in a dual-barrel configuration connected by a passageway. *See* Albright et al. col. 3, lines 38-45. The sleeve is inserted into tissue using a cutting tool that is disposed in the sleeve. Col. 4, lines 36-45. Once the sleeve is in position, the cutting tool is removed from the trailing, exposed end of the sleeve, and two needles and a plunger are inserted. Col. 4, lines 45-50. The plunger holds the two needles, and one end of a conventional suture is attached to each needle. When the plunger is depressed, the needles are pushed through the tissue to an exit point. When the needles emerge from the exit point, they may be pulled from the tissue, pulling each end of the suture through with them. Col. 4, lines 51-58. The suture is then tied off. Col. 5, lines 6-9.

The Applicants respectfully submit that the Examiner has failed to make a *prima facie* case of obviousness created by the combination of Buncke and Albright et al., because, as noted with respect to claims 46-54 above, at least two of the three basic criteria are not met. *See* MPEP § 2143. First, there is no suggestion or motivation to combine Buncke and Albright et al. Albright et al. teaches the use of conventional sutures that require tying, while Buncke does not require tying but rather relies on resistance along the barbed suture. Albright et al. also has a plunger as its means for advancing the needles, while Applicants’ invention does not have a plunger, but just a

thumb hold. Finally, Albright et al. requires two needles to function while Applicants' invention requires but one suture. As a result, any attempt to combine Buncke and Albright et al. does not result in Applicants' claimed invention.

Second, the cited references do not teach or suggest all of the claim limitations. Specifically, claim 55 recites manual grouping and advancing of tissue along the suture; this is an additional step that is not disclosed in Buncke, nor is it disclosed in Albright et al.

Claim 56 depends from claim 55, adds elements thereto, and is allowable for the reasons given above with respect to claim 55.

3. *Claim 57*

Initially, it should be noted that claim 57 depends from claim 55 and as such is believed to be allowable for the reasons discussed above. Nonetheless, for completeness, Applicants will address the rejection of claim 57 below.

The Examiner rejected claim 57 based on 35 U.S.C. § 103(a) obviousness as unpatentable over Buncke in view of Albright et al. and further in view of Coggins et al. Claim 57 is directed to a browlift. The Examiner indicated that Buncke in view of Albright et al. disclose the invention substantially as claimed, but does not disclose a browlift, and that Coggins et al. teaches a prosthesis and method for lifting various tissues in cosmetic procedures, including a face lift. The Examiner stated that "[i]t would have been obvious to one having ordinary skill in the art, at the time the invention was made, in view of Coggins et al., to apply the method Buncke in view of Albright et al. to the brow. Such a method would allow the lifting of a precise location as a brow, which is adjacent to tissues commonly lifted in a conventional face lift as disclosed by Buncke and Albright et al."

For the same reasons that Buncke and Albright et al. cannot be combined to establish a *prima facie* case of obviousness, and that Buncke and Coggins et al. cannot be combined to establish a *prima facie* case of obviousness, the three references cannot be combined. Claim 57 is allowable over the combined references.

The Applicants respectfully submit that the claimed cosmetic surgery procedures are not obvious in view of the prior art. Reconsideration and withdrawal of the rejection and allowance of claims 46-57 are requested.

For the foregoing reasons, the Applicants respectfully submit that the methods claimed in the present application are neither anticipated nor fairly taught or suggested by any of the references cited by the Examiner, either alone or in any reasonable combination suggested by the prior art. Reconsideration and withdrawal of the rejections

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and allowance of claims 45-57 at an early date are respectfully requested. Consideration and allowance of new claims 60-78 at an early date are also requested.

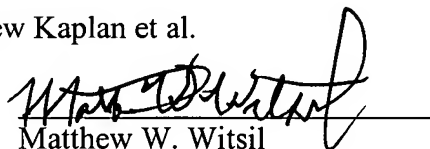
If the Examiner has any questions about the present Amendment or anticipates finally rejecting any claim of the present application, a telephone interview is requested.

Respectfully submitted,

Andrew Kaplan et al.

Date: January 10, 2005

By:


Matthew W. Witsil
Registration No. 47,183
Attorney for Applicants

Moore & Van Allen PLLC
430 Davis Drive, P.O. Box 13706
Research Triangle Park, NC 27709
Telephone: (919) 286-8000
Facsimile: (919) 286-8199